CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number : 074730

Trade Name : LOPERAMIDE HYDROCHLORIDE ORAL SOLUTION 1MG/5ML

Generic Name: Loperamide Hydrochloride Oral Solution 1mg/5ml

Sponsor : Morton Grove Pharmaceuticals, Inc.

Approval Date: August 28, 1997

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION 074730

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	Included	Pending Completion	Not Prepared	Not Required
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Bioequivalence Review(s)	X			
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CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 074730

APPROVAL LETTER

ANDA 74-730

AUG 28 1997

Morton Grove Pharmaeuticals, Inc.
Attention: Maurice E. Bordoni
6451 West Main Street
Morton Grove, IL 60053

Dear Sir:

This is in reference to your abbreviated new drug application dated August 14, 1995, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Loperamide Hydrochloride Oral Solution, 1 mg/5 mL.

Reference is also made to your amendments dated January 9, 1996; and June 27 and August 13, 1997.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted Over-The-Counter (OTC) labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Loperamide Hydrochloride Oral Solution, 1 mg/5 mL, to be bioequivalent to the listed drug (Imodium® A-D Liquid, 1 mg/5 mL of McNeil Consumer Products Co.).

Under 21 CFR 314.70, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Sincerely yours,

/S/

8/28/97

Douglas L. Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER 074730

FINAL PRINTED LABELING

28 1997

LOPERAMIDE HYDROCHLORIDE ORAL SOLUTION

Anti-Diarrheal

Original Prescription Strength

Controls the symptoms of diarrhea, including Travelers' Diarrhea.

Pleasant tasting cherry flavor.

Convenient dosage cup enclosed

Manufactured By:
Morton Grove Pharmaceuticals, Inc.
Morton Grove, IL 60053

BOXALL, INC.

MGP

NDC 60432-742-60

LOPERAMIDE HYDROCHLORIDE ORAL SOLUTION

Anti-Diarrheal

Controls the symptoms of diarrhea, including Travelers' Diarrhea

Original Prescription Strength

Cherry flavored

Store at room temperature

Each teaspoonful (5 mL) contains:
Loperamide HCl ..... 1 mg
Alcohol 5%

SAFETY SEALED BOTTLE

NET: 2 fl oz (60 mL)

N 3 60432-742-60 3

NDC 60432-742-60

LOPERAMIDE
HYDROCHLORIDE
ORAL SOLUTION

Original Prescription Strength

NET: 2 fl oz (60 mL)

LOPERAMIDE HYDROCHLORIDE ORAL SOLUTION

Anti-Diarrheal

Original Prescription Strength

Controls the symptoms of diarrhea, including Travelers' Diarrhea.

Pleasant tasting cherry flavor.

Convenient dosage cup enclosed

See top flap for expiration date.
Store at room temperature.

Manufactured By:
Morton Grove Pharmaceuticals, Inc.
Morton Grove, IL 60053

5-50-8742-60
ISS. 11-96

Loperamide hydrochloride oral solution is for the effective treatment of diarrhea. Loperamide hydrochloride oral solution relieves diarrhea, often in just one dose, in both adults and children 6 years and older.

INDICATIONS: Loperamide Hydrochloride Oral Solution controls the symptoms of diarrhea, including Travelers' Diarrhea.

DIRECTIONS: Use the enclosed dosage cup to accurately measure Loperamide Hydrochloride Oral Solution as noted below. Drink plenty of clear fluids to help prevent dehydration, which may accompany diarrhea.

	1st dose	2nd dose, if needed
ADULTS AND CHILDREN 12 YEARS OF AGE AND OLDER		

Take 4 teaspoonfuls (1 dosage cup) after the first loose bowel movement and 2 teaspoonfuls after each subsequent loose bowel movement but no more than 8 teaspoonfuls a day for no more than 2 days.

	1st dose	2nd dose, if needed
CHILDREN 9 TO 11 YEARS (60 TO 95 LBS)		

Take 2 teaspoonfuls (1/2 dosage cup) after the first loose bowel movement and 1 teaspoonful after each subsequent loose bowel movement but no more than 6 teaspoonfuls a day for no more than 2 days.

	1st dose	2nd dose, if needed
CHILDREN 6 TO 8 YEARS (48 TO 59 LBS)		

Take 2 teaspoonfuls (1/2 dosage cup) after the first loose bowel movement and 1 teaspoonful after each subsequent loose bowel movement but no more than 4 teaspoonfuls a day for no more than 2 days.

Children under 6 years old (up to 47 lbs): Consult a physician. Not intended for use in children under 6 years old.

WARNING: **KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.** Do not use for more than two days unless directed by a physician. **DO NOT USE IF DIARRHEA IS ACCOMPANIED BY HIGH FEVER (GREATER THAN 101 °F), OR IF BLOOD OR MUCUS IS PRESENT IN THE STOOL, OR IF YOU HAVE HAD A RASH OR OTHER ALLERGIC REACTION TO LOPERAMIDE HCl.** If you are taking antibiotics or have a history of liver disease, consult a physician before using this product. As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product. In case of accidental overdose, seek professional assistance or contact a poison control center immediately.

ACTIVE INGREDIENT: Loperamide HCl 1 mg per teaspoonful (5 mL).

INACTIVE INGREDIENTS: Citric Acid, USP; Flavors; Glycerin, USP; Methylparaben, NF; Propylparaben, NF; Purified Water, USP; Saccharin Sodium, USP; Sodium Citrate, USP and Sorbitol Solution, USP.

LOPERAMIDE HYDROCHLORIDE ORAL SOLUTION

Anti-Diarrheal

Original Prescription Strength

- **Controls the symptoms of diarrhea, including Travelers' Diarrhea.**
- **Pleasant tasting cherry flavor.**

Convenient dosage cup enclosed

Manufactured By:
Morton Grove Pharmaceuticals, Inc.
Morton Grove, IL 60053

BOXALL, INC.

MGP

NDC 60432-742-04

LOPERAMIDE HYDROCHLORIDE ORAL SOLUTION

Anti-Diarrheal
Controls the symptoms of diarrhea, including Travelers' Diarrhea
Original Prescription Strength
Cherry flavored
Store at room temperature

Each teaspoonful (5 mL) contains:
Loperamide HCl ..... 1 mg
Alcohol 5%

SAFETY SEALED BOTTLE

NET: 4 fl oz (118 mL)

N 3 60432-742-04 7

LOPERAMIDE HYDROCHLORIDE ORAL SOLUTION

Anti-Diarrheal

Original Prescription Strength

Controls the symptoms of diarrhea, including Travelers' Diarrhea.

Pleasant tasting cherry flavor.

Convenient dosage cup enclosed

See top flap for expiration date.
Store at room temperature.

Manufactured By:
Morton Grove Pharmaceuticals, Inc.
Morton Grove, IL 60053

5-50-8742-04
ISS. 11-96

NDC 60432-742-04

LOPERAMIDE HYDROCHLORIDE ORAL SOLUTION

Original Prescription Strength

NET: 4 fl oz (118 mL)

Loperamide hydrochloride oral solution is for the effective treatment of diarrhea. Loperamide hydrochloride oral solution relieves diarrhea, often in just one dose, in both adults and children 6 years and older.

INDICATIONS: Loperamide Hydrochloride Oral Solution controls the symptoms of diarrhea, including Travelers' Diarrhea.

DIRECTIONS: Use the enclosed dosage cup to accurately measure Loperamide Hydrochloride Oral Solution as noted below. Drink plenty of clear fluids to help prevent dehydration, which may accompany diarrhea.

ADULTS AND CHILDREN 12 YEARS OF AGE AND OLDER	**1st dose** 	**2nd dose, if needed** 
Take 4 teaspoonfuls (1 dosage cup) after the first loose bowel movement and 2 teaspoonfuls after each subsequent loose bowel movement but no more than 8 teaspoonfuls a day for no more than 2 days.		
CHILDREN 9 TO 11 YEARS (60 TO 95 LBS)	**1st dose** 	**2nd dose, if needed** 
Take 2 teaspoonfuls (1/2 dosage cup) after the first loose bowel movement and 1 teaspoonful after each subsequent loose bowel movement but no more than 6 teaspoonfuls a day for no more than 2 days.		
CHILDREN 6 TO 8 YEARS (48 TO 59 LBS)	**1st dose** 	**2nd dose, if needed** 
Take 2 teaspoonfuls (1/2 dosage cup) after the first loose bowel movement and 1 teaspoonful after each subsequent loose bowel movement but no more than 4 teaspoonfuls a day for no more than 2 days.		

Children under 6 years old (up to 47 lbs): Consult a physician. Not intended for use in children under 6 years old.

WARNINGS: **KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.** Do not use for more than two days unless directed by a physician. **DO NOT USE IF DIARRHEA IS ACCOMPANIED BY HIGH FEVER (GREATER THAN 101 °F), OR IF BLOOD OR MUCUS IS PRESENT IN THE STOOL, OR IF YOU HAVE HAD A RASH OR OTHER ALLERGIC REACTION TO LOPERAMIDE HCl.** If you are taking antibiotics or have a history of liver disease, consult a physician before using this product. As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product. In case of accidental overdose, seek professional assistance or contact a poison control center immediately.

ACTIVE INGREDIENT: Loperamide HCl 1 mg per teaspoonful (5 mL).

INACTIVE INGREDIENTS: Citric Acid, USP; Flavors; Glycerin, USP; Methylparaben, NF; Propylparaben, NF; Purified Water, USP; Saccharin Sodium, USP; Sodium Citrate, USP and Sorbitol Solution, USP.

Morton Grove Pharmaceuticals, Inc.
Morton Grove, IL 60053

LOPERAMIDE HYDROCHLORIDE ORAL SOLUTION
PRODUCT CODE 8742
FINAL PRINTED 2-FL OZ (60 mL) CONTAINER LABELING

MGP

NDC 60432-742-60

LOPERAMIDE HYDROCHLORIDE ORAL SOLUTION

Anti-Diarrheal
Controls the Symptoms of Diarrhea
Cherry flavored

Store at room temperature

Each teaspoonful (5 mL) contains:
Loperamide HCl ..... 1 mg
Alcohol 5%

DO NOT USE IF BAND PRINTED "SEALED FOR YOUR PROTECTION" AROUND CAP IS BROKEN OR MISSING.

NET: 2 fl oz (60 mL)

INDICATIONS: Loperamide Hydrochloride Oral Solution controls the symptoms of diarrhea, including Travelers' Diarrhea.

DOSAGE AND ADMINISTRATION: Use the dosage cup provided to accurately measure Loperamide Hydrochloride Oral Solution as directed below. Drink plenty of clear fluids to help prevent dehydration, which may accompany diarrhea.

ADULTS AND CHILDREN 12 YEARS OF AGE AND OLDER: Take 4 teaspoonfuls (1 dosage cup) after the first loose bowel movement and 2 teaspoonfuls after each subsequent loose bowel movement but no more than 8 teaspoonfuls in 1 day, or more than 2 days.

CHILDREN 9 TO 11 YEARS (60 TO 95 LBS): Take 2 teaspoonfuls (1/2 dosage cup) after the first loose bowel movement and 1 teaspoonful after each subsequent loose bowel movement but no more than 6 teaspoonfuls a day for no more than 2 days.

CHILDREN 6 TO 8 YEARS (40 TO 59 LBS): Take 2 teaspoonfuls (1/2 dosage cup) after the first loose bowel movement and 1 teaspoonful after each subsequent loose bowel movement but no more than 4 teaspoonfuls a day for no more than 2 days.

Children under 6 years old (up to 39 lbs): Consult a physician. Not intended for infants.

WARNINGS: **KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.** Do not use for more than two days unless directed by a physician. **DO NOT USE IF DIARRHEA IS ACCOMPANIED BY HIGH FEVER (GREATER THAN 101 °F), OR IF BLOOD OR MUCUS IS PRESENT IN THE STOOL. IF YOU HAVE HAD A RASH OR OTHER ALLERGIC REACTION TO LOPERAMIDE HCl.** If you are taking antibiotics or have a history of liver disease, consult a physician before using this product. As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product. In case of accidental overdose, seek professional assistance or contact a poison control center immediately.

INACTIVE INGREDIENTS: Loperamide HCl, Alcohol, Artificial Cherry Flavor, Citric Acid, USP, Flavors, Glycerin, USP, Methylparaben, NF, Propylparaben, NF, Purified Water, USP, Saccharin Sodium, USP, Sodium Citrate, USP and Sorbitol Solution, USP.

Manufactured By:
Morton Grove Pharmaceuticals, Inc.
Morton Grove, IL 60053
Stock 742-60
LSL 11-96

3 60432-742-60 3

Loperamide Hydrochloride Oral Solution
ANDA # 74-730

Morton Grove Pharmaceuticals, Inc.
Morton Grove, IL 60053

LOPERAMIDE HYDROCHLORIDE ORAL SOLUTION
PRODUCT CODE 8742
FINAL PRINTED 4-FL OZ (118 mL) CONTAINER LABELING

INDICATIONS: Loperamide Hydrochloride Oral Solution controls the symptoms of diarrhea, including Travelers' Diarrhea.

DIRECTIONS: Use the enclosed dosage cup to accurately measure Loperamide Hydrochloride Oral Solution as noted below. Drink plenty of clear fluids to help prevent dehydration, which may accompany diarrhea.

ADULTS AND CHILDREN 12 YEARS OF AGE AND OLDER: Take 4 teaspoonfuls (1 dosage cup) after the first loose bowel movement and 2 teaspoonfuls after each subsequent loose bowel movement but no more than 8 teaspoonfuls a day, or as directed by a doctor. Do not take for more than 2 days.

CHILDREN 9 TO 11 YEARS (60 TO 95 LBS): Take 2 teaspoonfuls (1/2 dosage cup) after the first loose bowel movement and 1 teaspoonful after each subsequent loose bowel movement but no more than 6 teaspoonfuls a day, or as directed by a doctor. Do not take for more than 2 days.

CHILDREN 6 TO 8 YEARS (48 TO 59 LBS): Take 2 teaspoonfuls (1/2 dosage cup) after the first loose bowel movement and 1 teaspoonful after each subsequent loose bowel movement but no more than 4 teaspoonfuls a day for no more than 2 days.

N 3 60432-742-04 7

MGP

NDC 60432-742-04

LOPERAMIDE HYDROCHLORIDE ORAL SOLUTION

Anti-Diarrheal
Controls the Symptoms of Diarrhea
Cherry flavored
Store at room temperature

Each teaspoonful (5 mL) contains:
Loperamide HCl ..... 1 mg
Alcohol 5%

DO NOT USE IF BAND PRINTED "SEALED FOR YOUR PROTECTION" AROUND CAP IS BROKEN OR MISSING.

NET: 4 fl oz (118 mL)

WARNINGS: **KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.** Do not use for more than two days unless directed by a physician. **DO NOT USE IF DIARRHEA IS ACCOMPANIED BY HIGH FEVER (GREATER THAN 101 °F), OR IF BLOOD OR MUCUS IS PRESENT IN THE STOOL, OR IF YOU HAVE HAD A RASH OR OTHER ALLERGIC REACTION TO LOPERAMIDE HCl.** If you are taking antibiotics or have a history of liver disease, consult a physician before using this product. As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product. In case of accidental overdose, seek professional assistance or contact a poison control center immediately.

ACTIVE INGREDIENT: Loperamide HCl 1 mg per teaspoonful (5 mL).

INACTIVE INGREDIENTS: Citric Acid, USP; Flavors; Glycerin, USP; Methylparaben, NF; Propylparaben, NF; Purified Water, USP; Saccharin Sodium, USP; Sodium Citrate, USP and Sorbitol Solution, USP.

Manufactured By:
Morton Grove Pharmaceuticals, Inc.
Morton Grove, IL 60053

50-8742-04
ISS. 11-96

Loperamide Hydrochloride Oral Solution
ANDA # 74-730

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER 074730

CHEMISTRY REVIEW(S)

1. CHEMISTRY REVIEW NO. 4

2. ANDA #74-730

3. NAME AND ADDRESS OF APPLICANT
Morton Grove Pharmaceuticals, Inc.
6451 West Main Street
Morton Grove, IL 60053

4. BASIS OF SUBMISSION
There are no patents that claim the referenced listed drug in this application.

5. SUPPLEMENT(s)
N/A

6. PROPRIETARY NAME
N/A

7. NONPROPRIETARY NAME
Loperamide HCl

8. SUPPLEMENT(s) PROVIDE(s) FOR:
N/A

9. AMENDMENTS AND OTHER DATES:

August 14, 1995--	Original Submission
September 20, 1995-	Acknowledgment letter
September 28, 1995-	New Correspondence
January 9, 1996--	Amendment
January 30, 1996--	Bio letter--Satisfactory
March 15, 1996--	Deficiency letter
April 25, 1996--	Amendment
September 18, 1996--	Deficiency letter
October 25, 1996--	Telecom--Chemistry
October 29, 1996--	Amendment
October 30, 1996--	Telecom--Labeling
November 13, 1996--	Telecom--Chem and Labeling
December 6, 1996--	Amendment (Labeling)
January 3, 1997--	Telecom--Chemistry
January 15, 1997--	Telecom Amendment
May 20, 1997--	MV Memo--Detroit District Lab--Def.
June 26, 1997--	Deficiency letter pertaining to the MV
June 27, 1997--	Amendment--MV
August 5, 1997--	MV Memo--Detroit District Lab--Acceptable with modifications
August 13, 1997--	Amendment--MV post-approval commitments

10. PHARMACOLOGICAL CATEGORY
Antidiarrheal

11. Rx or OTC
OTC

12. RELATED DMFs

(b)4 - Confidential Business

(b)4 - Confidential Business

13. DOSAGE FORM
Solution

14. POTENCY
1 mg/5 mL

15. CHEMICAL NAME AND STRUCTURE
4-(P-Chlorophenyl)-4-Hydroxy-N, N-Dimethyl-A, A-Diphenyl-1-Piperidinebutyramide

16. RECORDS AND REPORTS
N/A

17. COMMENTS
The post-approval drug product will be reformulated to reduce the alcohol content from (b)4 in compliance with 21 CFR 328.10 (telecom memo dated 10/25/96).

MV found acceptable with modifications. A post-approval commitment to validate the recommended modification (i.e., sample and standard should be prepared distinctly acidic) to the analytical method 8742A is appended.

18. CONCLUSIONS AND RECOMMENDATIONS
Recommend approval letter to issue.

19. REVIEWER:
/S/

DATE COMPLETED:
August 18, 1997

8/18/97

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER 074730

BIOEQUIVALENCE REVIEW(S)

DIV

OFFICE OF GENERIC DRUGS
DIVISION OF BIOEQUIVALENCE

ANDA/AADA #74-730 SPONSOR: Morton Grove
DRUG: loperamide hydrochloride
DOSAGE FORM: oral solution
STRENGTHS/(s): 1 mg/5 mL
TYPE OF STUDY: N/A

WAIVER:

The type and amount of active ingredient (loperamide hydrochloride), conditions of use, route of administration, dosage form, strength, and labeling for loperamide hydrochloride oral solution are identical to the RLD product Imodium A-D®. The test product and RLD formulations are not qualitatively identical. All excipient concentrations in the test formulation appear to be within approved limits (Inactive ingredients Guide, 10/93).

Therefore, waiver of in vivo bioequivalence requirements may be granted for the test product loperamide hydrochloride oral solution 1 mg/5 mL under 21 CFR 320.22(b)(3).

PRIMARY REVIEWER: James D. Henderson, Ph.D. BRANCH: II
INITIAL: /S/ DATE 1-22-96

BRANCH CHIEF: Rabindra N. Patnaik, Ph.D BRANCH: II
INITIAL: /S/ DATE 1/22/96

DIRECTOR, DIVISION OF BIOEQUIVALENCE:
Keith K. Chan, Ph.D.
INITIAL: /S/ DATE 1/24/96

ANDA 74-730

JVL Corporation
A Delaware Corporation
Attention: Doranne Frano
6451 West Main Street
Morton Grove IL 60053

JAN 30 1996

Dear Madam:

Reference is made to your abbreviated new drug application dated August 14, 1995, submitted pursuant to Section 505 (j) of the Federal Food, Drug and Cosmetic Act for Loperamide Hydrochloride Oral Solution, 1 mg/5 mL.

The following comments pertain **only** to bioequivalency issues in the August 14, 1995 submission.

> The Division of Bioequivalence has completed its review and has no further questions at this time.

Please note that the bioequivalency comments expressed in this letter are preliminary. The above bioequivalency comments may be revised after review of the entire application, upon consideration of the chemistry, manufacturing and controls, microbiology, labeling or other scientific or regulatory issues. A revised determination may require additional information and/or studies, or may conclude that the proposed formulation is not approvable.

Sincerely yours,

/S/

Keith K. Chan, Ph.D.
Director, Division of Bioequivalence
Office of Generic Drugs
Center for Drug Evaluation and Research

JAN 2 2 1996

Loperamide Hydrochloride
1 mg/5 mL oral solution
ANDA #74-730
Reviewer: James D. Henderson
File: 74730W.895

Morton Grove Pharmaceuticals
Morton Grove, IL
Submitted:
August 14, 1995

REVIEW OF A WAIVER REQUEST

Background:

The sponsor has submitted an ANDA for it test product loperamide hydrochloride oral solution 1 mg/5 mL. The reference listed drug (RLD) is Imodium A-D® 1 mg/5 mL (McNeil Consumer Products, NDA #19-487, approved 3/1/88). In the Orange Book, 15th ed., 1995, p. 3-309, the RLD is listed under the dosage form heading "solution; oral".

Comments:

1. The sponsor states that the type and amount of active ingredient (loperamide hydrochloride), conditions of use, route of administration, dosage form, strength, and labeling for loperamide hydrochloride oral solution are identical to the RLD product Imodium A-D®.

2. The sponsor requests waiver of in vivo bioequivalence study requirements based on the following conditions of 21 CFR 320.22(b)(3):

- the test product and RLD are both oral solutions containing the same AI in the same concentration and dosage form
- The test product contains no inactive ingredient or other change in formulation from the RLD that may significantly affect absorption of the AI.

3. The test and reference product formulations are shown in Table 1. The formulations are not qualitatively identical. All excipient concentrations in the test formulation appear to be within approved limits (see footnotes to Table 1).

Recommendation:

The Division of Bioequivalence agrees that the information submitted by Morton Grove Pharmaceuticals demonstrates that loperamide hydrochloride oral solution 1 mg/5 mL falls under 21 CFR Section 320.22(b)(3) of the Bioavailability/Bioequivalence Regulations. The waiver of <u>in vivo</u> bioequivalence study for the test product 1 mg/5 mL oral solution is granted. From the bioequivalence point of view, the test product is deemed bioequivalent to the reference product Imodium® A-D (oral solution 1 mg/5 mL) manufactured by McNeil Consumer Products.

/S/

James D. Henderson, Ph.D.
Review Branch II
Division of Bioequivalence

RD INITIALED RPATNAIK
FT INITIALED RPATNAIK

/S/ 1/22/96

JDH/gj/1-22-96/74730

cc: ANDA #74-730 (original, duplicate), HFD-600 (Hare), HFD-630, HFD-344 (CViswanathan), HFD-655 (Patnaik, Henderson), Drug File, Division File